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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,790	07/26/2006	Francis Chi	OBL103CXC1	6044

23557 7590 02/02/2010

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
02/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,790	CHI ET AL.	
	Examiner	Art Unit	
	Brian-Yong S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *18 and 20-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 20-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 24, 25 and 28 are currently pending for prosecution on the merits.

Acknowledgement is made of applicant's amendment/remarks on 12/29/2009. By the amendment, claims 18 and 20 have been amended and claim 27 has been newly added.

2. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 18, 20-22 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernton et al. (US 5605885).

Bernton teaches the administration of prolactin agonist (e.g., cysteamine or cysteamine hydrochloride), singly or in combination with other agent (e.g., cyclosporine), to an animal or human thereby preventing or treating the deleterious effects of stress (e.g., psychosocial stress

such as bereavement), or to stimulate immune, or bone marrow function, namely antagonizing suppression of immune function by chronic stress or prevention or treatment of stress induced impairment of the immune system, wherein said cysteamine is administered orally once or twice each day to achieve adequate immunostimulation in approximately 1 to 25 mg per kg body weight (column 2, line 64 through column 3, line 27 and 64-67; column 5, lines 5-8 and lines 60-62; column 8, lines 61-65; column 4, lines 17-23; column 10, line 52 through column 11, line 53; Example 1).

Although Bernton is silent about the functional property of cysteamine in maintaining or lowering endogenous cortisol level, such property deems to be inherent to the referenced method. It is noted that the prior art method directing the administration of same compound (i.e., prolactin like compound such as cysteamine or cysteamine hydrochloride) to same patient population, in overlapping dosage amounts, inherently possessing same therapeutic utility for the ultimate purpose as disclosed by the applicant anticipates the instant invention even explicit recitation of underlying mechanism.

To the extent that the claims 18-22 and 24-26 include the active step of administering cysteamine to the patient prior to the stressful event, the instant invention is construed to mean the absolute absence of stress event. In other words, the analysis of the instant claims 18-22 and 24-26 allows for the inclusion of any patient population other than the stressful event, as long as the same compound is administered to body of the patient in overlapping dosage amounts. The examiner determines that the prior art patient taking opioid or glucocorticoid falls within "metes and bounds" of the instant patient population without the stressful event, and thus Bernton anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bernton et al. (US 5605885) in view of McCleary (US 6964969).

The teaching of Bernton has been discussed in above 35 USC 102(b) rejection.

McCleary is being provided as a supplemental reference to demonstrate the routine knowledge in using therapy such as relaxation, massage, acupuncture, psychotherapy, meditation, taking a sedative and the like for the treatment of stress (column 21, lines 3-14).

The teaching of Bernton differs from the claimed invention in the use of cysteamine and therapy (e.g., counseling, psychotherapy, exercise, meditation and massage therapy).

Above references in combination make clear that cysteamine and therapy such as relaxation, massage, acupuncture, psychotherapy and meditation have been individually used for the treatment of stress. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

Response to Arguments

5. Applicant's arguments filed 12/29/20009 have been fully considered but they are not persuasive.

Applicant's argument in the response takes the similar position as to the previous argument filed 06/16/2009 that Bernton fails to teach administering cysteamine, or a salt thereof, to a patient prior to a stressful event in order to maintain or reduce cortisol in the patient following the stressful event. Applicant asserts that Benton has not teaching or suggestion regarding the ability of cysteamine, when administered to a patient prior to a stressful event, to maintain or lower cortisol levels following the stressful event and that the findings of Benton essentially teach away from the methods of the claimed invention since Bernton essentially teach

administering cysteamine to ensure adrenal sufficiency, including the ability to increase cortisol levels in the immunosuppressed patient.

This argument is not found persuasive. Although the examiner recognizes the potential benefit of using prolactin agonist (e.g., cysteamine or a salt thereof) in preventing the impairment of adrenal cortical secretory functions in patients who have been chronically treated with exogenous glucocorticosteroids or synthetic analogs in the cited reference, Bernton also identify that patients with "chronic severe stress", and "critically ill patients such as those with severe burns or complications of sepsis or of multiple trauma…" (column 2, line 65 through column 1, line 17; column 5, lines 60-63) are the suitable treatment population of the instant invention and discloses that the administration of the prolactin (e.g., cysteamine or a salt thereof) would provide a treatment for stress induced impairment of the immune system. Since the substantial portion of patients encompassed by Bernton, which is an immunosuppressed animal or human associated with stress or stressful event (which is a physical, mental, or emotional response that causes bodily or mental situation, for example severe burns or multiple trauma, psychosocial stress or bereavement, cancers, infections, etc…), distinguish from the subset of patient with the impairment of adrenal cortical secretory functions, the examiner determines that the functional property of cysteamine in maintaining or lowering endogenous cortisol level deems to be inherent to the immunosuppressed animal or human associated with stress or stressful events. One having ordinary skill in the art would have understood, reading the entire context of Bernton, that the impaired immune response associated with stress or stressful event which is due, in part, to an increased secretion of adrenal corticosteroids from the adrenal glands in response to stress or stressful event, would be benefited from the administration of the prolactin

(cysteamine or a salt thereof). Thus, the prior art method directing the administration of same compound (i.e., prolactin like compound such as cysteamine or cysteamine hydrochloride) to same patient population, in overlapping dosage amounts, inherently possessing same therapeutic utility for the ultimate purpose as disclosed by the applicant anticipates the instant invention even explicit recitation of underlying mechanism.

Anticipation under 35 USC 102 is an essentially irrebuttable question of fact, wherein the court stated that anticipation "cannot be overcome by evidence of unexpected results or teachings away in the art". *In re Malagari, 499 F.2d 1289, 182 USPQ; In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Alternpohl, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973); In re Wilder, 429 F.2d 447, 166 USPQ 545 (CCPA 1970).* Indeed, a reference might reside in a nonanalogous art and yet constitute an anticipation of a claimed invention under 35 USC 102. *In re Self, 571 F.2d 134, 213 USPQ 1 (CCPA 1982).* .In this case, the prior art method directing the administration of same compound (i.e., prolactin like compound such as cysteamine or cysteamine hydrochloride) to same patient population (e.g., patient taking glucocorticosteoids or opioid), in overlapping dosage amounts, inherently possessing same therapeutic utility for the ultimate purpose as disclosed by the applicant anticipates the instant invention even explicit recitation of underlying mechanism.

Applicant's argument in response to the 35 USC 103 rejection is basically the same as discussed above, so the response discussed above applies here as well and is unpersuasive for reason just discussed

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system,

see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614